Informed Consent for HIV Testing in a South African Hospital: Is It Truly Informed and Truly Voluntary?

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ABSTRACT

Objective. The purpose of this study was to assess informed consent to human immunodeficiency virus (HIV) testing in a perinatal HIV transmission study in a major referral hospital serving a largely Black population in South Africa.

Methods. First-time antenatal clinic attenders who were randomly selected from those enrolled in the perinatal HIV study (n = 56) answered questionnaires before and after counseling.

Results. Knowledge of HIV transmission and prevention, high at the outset, was little improved after counseling. The acceptance rate for HIV testing was high. Despite assurances that participation was voluntary, 88% of the women said they felt compelled to participate in the study.

Conclusions. Informed consent in this setting was truly informed but not truly voluntary. (*Am J Public Health.* 1998;88:637–640)

Introduction

In South Africa, a designated ethics review committee, analogous to an institutional review board in the United States, is routinely required to review ethical aspects of any proposed study in institutions involved in biomedical research. These boards or committees follow guidelines, which are usually based on widely accepted ethical principles,[1] but are seldom charged with evaluating the extent to which proposed ethical procedures achieve their intended results. This study is a novel attempt to carry out an assessment of one specific requirement, namely, the degree to which informed consent is truly informed and truly voluntary.

The emergence of the human immunodeficiency virus (HIV) pandemic has placed new imperatives on ethical standards in relation to informed consent for medical investigations because of the adverse social consequences associated with being HIV infected.[2] Pretest counseling has become the accepted ethical norm[3] in both routine clinical practice and research. The purpose of the counseling is to help individuals arrive at independent decisions, based on understanding and knowledge, as to whether or not to give consent to be tested.

Informed consent implies that the researcher and participant have entered into a voluntary agreement without any element of coercion and that the participant is fully knowledgeable of the implications of participation.[4] Four principles underpin ethical norms in biomedical research. Autonomy, beneficence, nonmaleficence, and justice are principles based on the 1975 Declaration of Helsinki and the 1947 Nuremberg Code.[5] They aim to ensure that the participant understands the research sufficiently to make an enlightened decision, that the participant endures no harm, that the research contributes to the general welfare and health, and that recruitment respects the concept of fairness.

The Departments of Paediatrics and of Obstetrics and Gynaecology of the University of Natal collaborated in a linked HIV seroprevalence survey among first-time antenatal clinic attenders at King Edward VIII Hospital, Durban, to recruit a cohort of HIV-positive women into a perinatal HIV transmission study.[6] The current study of informed consent was undertaken in light of the serious implications of a positive HIV result for a pregnant woman in such matters as the continuation of the pregnancy and disclosure of HIV status to her partner(s).

Methods

Approval for this study was obtained from the Ethics Committee of the Faculty of Medicine, University of Natal. Permission to undertake this study was obtained from the Chief Medical Superintendent of King Edward VIII Hospital, Durban.

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This paper was accepted January 8, 1998.

The Perinatal HIV Transmission Study

Since 1991, first-time antenatal clinic attenders at King Edward VIII Hospital have been invited to participate in the perinatal HIV transmission study. Each weekday morning, all first-time antenatal clinic attenders in the waiting area are provided with information on HIV/AIDS and the perinatal HIV transmission study. An experienced AIDS counselor lectures groups of about 40 women in sessions of about 30 minutes. All who agree to participate sign a consent form confirming that they understand what they are consenting to and that they participate of their own volition. Blood for HIV testing is then drawn. At the second visit, HIV-positive women only are recruited into the perinatal HIV transmission study and counseled again in greater detail.

Study Design

To evaluate the informed consent obtained, we used a before-and-after design. An evaluation study group (n = 56) completed questionnaires before and after the counseling session; a sensitization control group (n = 56) completed only a postcounseling questionnaire. Consent for participation in this study was also sought from both groups of women before administration of the questionnaire.

Questionnaires were administered before and after counseling to 56 women randomly selected from the first-time antenatal clinic attenders who had consented to participate in the perinatal HIV transmission study. To measure the sensitizing effect of the precounseling questionnaire, the postcounseling questionnaire alone was also administered to another random sample of 56 women recruited into the perinatal HIV transmission study. Data were collected using previously piloted standardized questionnaires specifically designed for the study. The precounseling questionnaires included items on knowledge of AIDS; misconceptions about HIV transmission and prevention; aspects of HIV testing; and the personal, medical, and social implications of being diagnosed as HIV positive. The postcounseling questionnaire included, in addition, items that measured issues relating to participation in the perinatal HIV transmission study; for example, was consent voluntary, did the respondent understand the implications of participation, and what were the respondent's perceptions of the effects of nonparticipation on the quality of care received.

TABLE 1—Perceptions of HIV/AIDS in Evaluation Study Group (Before and After Counseling) and Sensitization Control Group (After Counseling Only) of Antenatal Clinic Attenders: Durban, South Africa

	Affirmative Responses, %		
	Precounseling (n = 56)	Postcounseling (n = 56)	Control (n = 56)
Modes of transmission			
Vertical transmission	98	95	95
Sexual transmission	100	100	98
Breast-feeding	23	20	29
Casual contact	11	7	4
Methods of prevention			
Fewer partners	96	98	100
Use of condoms	98	96	100
Good food	7	2	4
Nature of infection			
AIDS is fatal	96	98	100
AIDS can be cured	11	16	0
Infected person can look healthy	14	13	7
Need a blood test to know HIV status	7	9	7
Would like to have a blood test	80	. . .	. . .
HIV-infected individual			
Able to work	86	93	70
Able to take care of her baby	71	70	66
Has a positive outlook on life	0	4	4

Study Procedure

At each weekday morning session during the study period, before group counseling for the perinatal HIV transmission study, the precounseling questionnaire was administered to 2 women randomly selected for the evaluation study group. The postcounseling questionnaire was administered to the same 2 women within 2 hours of the perinatal HIV transmission study counseling. The postcounseling questionnaire was administered also to 2 other women randomly selected at the same time for the sensitization control group.

All questionnaires were administered by the same trained fieldworker in either English or Zulu, depending on the respondent's preference. The counselor for the perinatal HIV transmission study was "blind" to this evaluation until after the study was completed, and the interviewer for the current study was "blind" to the content of the perinatal HIV transmission study counseling session.

Data Analysis

All data were recorded in English on standardized questionnaires. Open-ended questions were coded for content and treated as categorical variables. Matched pair analysis was undertaken to compare each woman's knowledge before and after counseling. The sensitizing effect of the questionnaire was assessed using Fisher's exact test by comparing the postcounseling responses of women in the evaluation study group with those of women in the sensitization control group.

Results

The response rate was 100% for both the evaluation study group and the sensitization control group. The average age of the evaluation study group was 26.6 years (range = 16 to 42 years, standard deviation [SD] = 5.8). The average age of the sensitization control group was 27.1 years (range = 15 to 38 years; SD = 5.8, P = NS). On average, the evaluation study group participants had 10.1 (SD = 1.6) years of education and the sensitization control group 9.5 (SD = 2) years (P = NS).

Pre- and Postcounseling Comparisons in the Evaluation Study Group Relating to Their Knowledge of HIV Infection

Overall, a high proportion of study subjects responded correctly to the questions relating to HIV knowledge before they were counseled. There was little change in these proportions after the counseling session; no statistically significant differences were found (Table 1). In the evaluation study

group, 100% reported awareness of sexual transmission of HIV and 98% reported awareness of vertical transmission of HIV before counseling compared with 100% and 95%, respectively, after counseling. Before counseling, partner reduction and the use of condoms were indicated as methods of preventing the spread of AIDS by 96% and 98% of the group, respectively, and after counseling by 98% and 96%, respectively. Ninety-six percent considered AIDS to be fatal before counseling and 95% after counseling. As to voluntary HIV testing, 80% of the evaluation study group indicated that they would have volunteered for an HIV test if it had been offered. However, only 7% thought a blood test necessary to determine HIV status.

Perceived Implications of an HIV Test; Pre- and Postcounseling Comparisons in the Evaluation Study Group (Table 2)

Two percent of the women before counseling, and none after, thought sickness would soon follow on a positive test. Both before and after the counseling, almost all women intended to use condoms and to reduce the number of partners regardless of HIV test result. In response to an open-ended question about the perceived social implications of a positive test, before counseling 91% thought that they would lose their partners, after counseling, 93%; before counseling, 39% thought that they would lose their jobs, after counseling, 29%; before counseling, 29% thought that they would face job discrimination, after counseling, 16%; before counseling, 16% thought that they would lose family support, after counseling, 16%. The only statistically significant difference between the pre- and postcounseling responses related to the benefit of an HIV test. Before counseling, 59% of the group saw personal knowledge of their HIV status as a benefit, after counseling, 36%.

Was Consent Obtained for HIV Testing? (Table 3)

Eighty-eight percent of the evaluation study group and 93% of the sensitization control group agreed to HIV testing. Eighty-six percent and 91% also said that they would like to know their HIV test result. Eighty-four percent of the evaluation study group and 93% of the sensitization control group thought that it was compulsory to be tested. While 93% of the women from the evaluation study group and 88% from the sensitization control group thought that they were free to quit the study at any time, 98% of the evaluation study group and the entire sensitization control group believed that the hospital would not allow them to quit. Furthermore, 32% of the evaluation study group and 23% of the sensitization control group thought that the care they received at the hospital would change if they did not participate in the perinatal HIV transmission study.

TABLE 2—Implications of HIV Test Results as Perceived by Evaluation Study Group (Before and After Counseling) and by Sensitization Control Group (After Counseling) of Antenatal Clinic Attenders: Durban, South Africa

	Affirmative Responses, %		
	Precounseling (n = 56)	Postcounseling (n = 56)	Control (n = 56)
Benefits of blood test			
Assurance of HIV status	59*	36*	36
Disadvantages of blood test			
Progression to disease and death	2	0	2
Negative test result = no AIDS	13	7	13
Implications for behavior change			
Positive test result			
Intend to reduce partner number	100	98	100
Intend to use condoms	96	96	96
Negative test result			
Intend to reduce partner number	100	98	100
Intend to use condoms	100	98	100
Social implications of a positive test result			
Loss of partner	91	93	82
Loss of job	39	29*	48*
Job discrimination	29	16*	36*
Loss of family support	16	16	13

*$P < .05$ for differences between marked groups.

TABLE 3—Perceptions of Consent Given for Participation in Informed Consent Study: Evaluation Study Group vs Sensitization Control Group of Antenatal Clinic Attenders in Durban, South Africa

	Affirmative Responses, %	
	Study Group (n = 56)	Controls (n = 56)
Did you agree to have an HIV antibody test?	88	93
Do you want to know your HIV test result?	86	91
Did you feel you were compelled to participate in the study?	84	93
Will care be compromised if you do not participate?	32	23
Having agreed to participate in the study, do you think that you have the freedom to quit the study at any time?	93	88
Will the hospital allow you to quit?	2	0

Did the Precounseling Questionnaire Have a Sensitizing Effect? (Tables 1–3)

In the postcounseling questionnaire administered to both the evaluation study group and the sensitization control group, the proportions of subjects who responded correctly to questions relating to HIV knowledge and implications of a positive HIV test were similar. Only 7% of the evaluation study group and 13% of the sensitization control group understood that a negative test indicated no current HIV infection. The difference was not statistically significant. Statistically significant differences between the postcounseling study and control group responses were found only on the 2 job-related questions. Women from the control group were more likely to indicate that a positive HIV test result would lead to job discrimination and loss of employment than women from the evaluation study group ($P < .05$).

Discussion

In matters of knowledge about HIV, the women in this South African study were

well informed. As to the implications of testing positive, large proportions foresaw drastic consequences in loss of partners; substantially smaller proportions foresaw such consequences in regard to job or family. Counseling had minimal effects on their knowledge and perceptions about HIV. The drastic and disturbing findings of this small and simple study bear on the nature of informed consent.

Was the Consent Truly Informed?

Since, at the outset, the women in the study were already well informed, counseling could make little difference in improving knowledge. Other local studies found similar high levels of knowledge.[7–9] For the purposes of this study, knowledge of the main issues in the transmission and prevention of HIV can be considered adequate.

Was the Consent Truly Voluntary?

The acceptance rate for HIV testing was high. Although women were routinely assured that their participation in the study was entirely voluntary, 88% felt compelled to participate. This contrasts with the finding that 88% of those who agreed to testing wanted to know their HIV status, suggesting that volunteers saw value in the result. In other countries, such as in England, many women who attended antenatal clinics and agreed to the HIV test also did not want to know the result. Miller et al.[10] offered voluntary testing to 4929 women; 45% did not wish to know the result. In London antenatal clinics, only 12% of HIV-positive women have been identified by named testing.[11]

Twenty-eight percent of the women in our study perceived the research to be integral with service at the hospital and agreed to the HIV test because they thought that refusal would compromise their care. This subtle coercive element may stem from the social context of a hospital where the health professionals are held in high regard. This perception of potentially compromised quality of care is reinforced by the perception that the hospital would not allow them to quit the study even though they knew they had the freedom to do so. A qualitative study could add deeper understanding of these perceptions.

Conclusion

This medical service setting, and perhaps particularly public care, where the patient has little recourse to alternatives, influenced decisions to participate in a research project. Informed consent sought under such conditions may be less than voluntary. For the patients, an overriding concern is to receive care and attention for the problems that brought them there in the first place. In hospital-based research, many patients perceive that the hospital staff expect them to participate in the studies; this perception seems to have added a subtle element of coercion to ostensibly voluntary consent. This element of coercion may not be unique to this study nor to South Africa. It could well apply broadly, in both developing and developed countries, to studies undertaken in settings where services are sought by the poor and disadvantaged.

As Henry Sigerist and Talcott Parsons described many decades ago, patients relinquish autonomy to professional authority in the expectation of competence.[12–15] Informed consent is one of the safeguards that provide protection against exploitation when autonomy is relinquished. It is therefore important that consent be truly informed and truly voluntary.

These admittedly limited data provide empiric evidence that subtle and unexpected elements of coercion can reside in the perceptions (real or imagined) held by patients being recruited into a research project in a medical care setting. Replications to test these results are called for. Also, preventive measures need to be considered. The prerecruitment counseling and patient information sheet for research conducted on patients seeking medical care could include a statement explicitly stating that nonparticipation in the research project will in no way compromise the care provided at the institution. Counselors, caregivers, and researchers could be alerted to the potential problems and sensitized to them. Ethicists and institutional review boards should certainly explore the issue further. □

Acknowledgements

We thank Ms E. Gouws and Ms S. Sewambar for assistance with the statistical analysis, Ms Z. Gwamanda for the administration of the questionnaires, and Dr Z. Stein and Ms H. Fourie for their valuable assistance with this project. This study was funded by the South African Medical Research Council and Fogarty International Centre Grant TWO-0231.

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